K000228

FEB 22 2000

Special 510(k)
Summary of Safety and Effectiveness
ArthroCare Corporation
ENTec™ Surgery System

Manufacturer:	ArthroCare, Corporation 595 North Pastoria Avenue Sunnyvale, CA 94086-2916
Establishment Registration Number:	2951580
Contact Person:	Bruce Prothro Vice President, Regulatory Affairs and Quality Assurance
Date Prepared:	January 25, 2000

Device Description

Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Trade Name:	ENTec™ Surgery System
Generic/Common Name:	Electrosurgical Device and Accessories

Predicate Devices

ArthroCare Electrosurgery System	K973478; cleared on January 9, 1998

Intended Use

The ArthroCare Electrosurgery System is indicated for ablation and coagulation of soft tissue in otolaryngological (ENT) surgery including head, neck, oral, and sinus surgery.

Product Description

The ENTec Surgery System is a bipolar, high frequency electrosurgical System consisting of three components: an electrosugical generator called the Controller, the reusable Cable, and the disposable Wand.

Substantial Equivalence

This special 510(k) proposes modifications in materials and performance specifications to the Wand component of the ENTec Surgery System, which was previously cleared in K973478 on January 9, 1998 . The proposed modifications are only applicable to the Wand components of the System. The technology, principle of operation and the intended use of the entire System remain the same as in the original cleared 510(k).

Summary of Safety and Effectiveness

The ENTec Surgery System modified Wands, described in this submission, are substantially equivalent to the predicate, unmodified Wands. The proposed modifications in materials and performance specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2000

Mr. Bruce Prothro
Vice President, Regulatory Affairs and Quality Assurance
Arthrocare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086

Re: K000228
Trade Name: ENTec™ Surgery System
Regulatory Class: II
Product Code: GEI
Dated: January 25, 2000
Received: January 27, 2000

Dear Mr. Prothro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: ENTec™ Surgery System
510(k) Number: K000228

Indications for use:

The ENTec™ Surgery System is indicated for ablation and coagulation of soft tissue in otolaryngological (ENT) surgery including head, neck, oral, and sinus surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000228

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)